

EXHIBIT B

-----Original Message-----

From: Calder, Courtney [mailto:CalderC@cder.fda.gov]
Sent: Thursday, October 27, 2005 3:17 PM
To: Patel, Manini
Subject: : Neurontin clarification by phone request

Hi Manini,
Regarding your phone call, below are our answers:

1. We think that "suicidal" should be deleted because its meaning is unclear. It is not clear what, as an adjective, it is referring to since there is no noun following it.
2. "Suicide gesture" is a less clear term than "suicide attempt." If interpreted as meaning "suicide attempt," the current placement of the term with respect to the frequency of its occurrence in clinical trials is incorrect. According to the analysis submitted in September, 2004, suicide attempts occurred in .12% of patients participating in non-placebo-controlled adult add-on epilepsy trials and 0.17% of patients in adult add-on placebo-controlled studies. Therefore, "suicide attempt" should be listed as an infrequent adverse event.
3. Because suicides occurred in 0.02% of patients participating in non-placebo-controlled adult add-on epilepsy trials, suicide should be listed as a rare adverse event in this section (describing events that occurred in adult add-on epilepsy trials).

I hope this answers your questions.

Sincerely,

Courtney

Courtney R. Calder, Pharm.D., LT USPHS
Regulatory Project Manager
Division of Neurology Products, HFD-120
Center For Drug Evaluation and Research, FDA
Office of Drug Evaluation I
Ph: (301) 796-1050
Fax: (301) 796-9842
Email: calderc@cder.fda.gov